



DEPARTMENT OF THE NAVY
NAVAL MEDICAL COMMAND
WASHINGTON, D.C. 20372-5120

IN REPLY REFER TO
NAVMEDCOMINST 6710.14
MEDCOM-313
17 Aug 87

NAVMEDCOM INSTRUCTION 6710.14

From: Commander, Naval Medical Command

Subj: ACCEPTANCE OF PHARMACEUTICAL SAMPLES ON A TRIAL BASIS

Ref: (a) SECNAVINST 5370.2H
(b) SECNAVINST 4001.2E

1. Purpose. To provide guidance for accepting pharmaceutical samples for trial.

2. Background. Acceptance of free pharmaceutical samples from sales representatives for trial is a common practice by civilian practitioners. When done individually by Navy Medical Department personnel, such acceptance of samples is in violation of references (a) and (b). To control the Navy drug sampling system and to ensure appropriate medical record entries, guidelines are required that will fully protect patient health, prevent conflicts of interest, and prevent appearances of preferential treatment.

3. Scope. This instruction applies to activities under the command of the Commander, Naval Medical Command who elect to accept free pharmaceutical samples.

4. Action

a. Vendors offering trial samples will be directed to the pharmacy department. The head of the pharmacy department will direct a review by the Pharmacy and Therapeutics Committee (P and T), or similar committee. Requests for trial use must include the following information:

- (1) Name and strength of the drug.
- (2) Name and address of the manufacturer.
- (3) Brief description of the item.
- (4) Function.
- (5) Location of the proposed trial.
- (6) Length of the trial period.
- (7) Estimated frequency of use during the trial period.
- (8) Reason for the trial.

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(9) Name of the principal evaluator.

(10) Persons authorized to prescribe for use.

(11) Price of the drug, in anticipation of formulary acceptance.

b. The P and T Committee will ensure that the following conditions are met before approving samples for acceptance.

(1) Samples are accepted at no cost to the Government.

(2) Acceptance for trial implies no agreement to purchase.

(3) All test evaluations are the property of the U.S. Government and will not be used by industry as endorsements of their products.

(4) Experimental drugs and controlled substances may not be included as a pharmaceutical sample trial.

c. After approval and acceptance, the principal evaluator will ensure that trial samples are delivered to pharmacies, dispensed by prescription, and appropriately documented. Prescribers will not personally dispense trial medications obtained from sales representatives. Prescriptions of smaller starter dose quantities are suggested for patients, to determine the value of the medication's effect before dispensing the remaining therapeutic course.

d. When the trial is completed, the principal evaluator will prepare a memorandum to the P and T Committee with comments that compare the item with similar pharmaceuticals. After reviewing the information in paragraph 4a and evaluator comments, the P and T Committee will advise the Head of the Pharmacy Department to include or exclude the item from the formulary.


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